

# PRIOR AUTHORIZATION CRITERIA

DRUG CLASS	TESTOSTERONE PRODUCTS (BRAND AND GENERIC)
BRAND NAME (generic)	<p><b>ANDRODERM</b> (testosterone transdermal patch)</p> <p><b>ANDROGEL</b> (testosterone topical gel)</p> <p><b>AXIRON</b> (testosterone topical solution)</p> <p><b>DELATESTRYL</b> (testosterone enanthate injection)</p> <p><b>DEPO-TESTOSTERONE</b> (testosterone cypionate injection)</p> <p><b>FORTESTA</b> (testosterone topical gel)</p> <p><b>NATESTO</b> (testosterone nasal gel)</p> <p><b>STRIANT</b> (testosterone mucoadhesive buccal system)</p> <p><b>TESTIM</b> (testosterone topical gel)</p> <p><b>TESTOPEL</b> (testosterone propionate implant pellets)</p> <p>(testosterone cream)</p> <p>(testosterone ointment)</p> <p><b>VOGELXO</b> (testosterone topical gel)</p>

**Status: CVS Caremark Criteria**  
**Type: Initial Prior Authorization**

## **POLICY**

### **FDA-APPROVED INDICATIONS**

Topical, buccal, nasal, implant, and injectable testosterone products are indicated for replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone.

Primary hypogonadism (congenital or acquired) - testicular failure due to conditions such as cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchiectomy, Klinefelter Syndrome, chemotherapy, or toxic damage from alcohol or heavy metals. These men usually have low serum testosterone concentrations and gonadotropins (FSH, LH) above the normal range.

Hypogonadotropic hypogonadism (congenital or acquired) - gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency or pituitary-hypothalamic injury from tumors, trauma, or radiation. These men have low testosterone serum concentrations but have gonadotropins in the normal or low range.

### **Limitations of Use**

Safety and efficacy of topical, buccal, nasal, implant, and injectable testosterone products in men with "age-related hypogonadism" (also referred to as "late-onset hypogonadism") have not been established.

Safety and efficacy of topical, buccal, nasal, implant, and injectable testosterone products in males less than 18 years old have not been established.

Topical testosterone products may have different doses, strengths or application instructions that may result in different systemic exposure.

### **Delatestryl**

#### **Males**

Delatestryl (Testosterone Enanthate Injection) is indicated for replacement therapy in conditions associated with a deficiency or absence of endogenous testosterone.

Primary hypogonadism (congenital or acquired) - testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, or orchiectomy.

Hypogonadotropic hypogonadism (congenital or acquired) - gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency, or pituitary-hypothalamic injury from tumors, trauma, or radiation. (Appropriate adrenal cortical and thyroid hormone replacement therapy are still necessary, however, and are actually of primary importance).

If the above conditions occur prior to puberty, androgen replacement therapy will be needed during the adolescent years for development of secondary sexual characteristics. Prolonged androgen treatment will be required to maintain sexual characteristics in these and other males who develop testosterone deficiency after puberty.

Safety and efficacy of Delatestryl in men with "age-related hypogonadism" (also referred to as "late-onset hypogonadism") have not been established.

Delayed puberty - Delatestryl (Testosterone Enanthate Injection) may be used to stimulate puberty in carefully selected males with clearly delayed puberty. These patients usually have a familial pattern of delayed puberty that is not secondary to a pathological disorder; puberty is expected to occur spontaneously at a relatively late date. Brief treatment with conservative doses may occasionally be justified in these patients if they do not respond to psychological support. The potential adverse effect on bone maturation should be discussed with the patient and parents prior to androgen administration. An X-ray of the hand and wrist to determine bone age should be obtained every six months to assess the effect of treatment on the epiphyseal centers.

#### **Females**

Metastatic Mammary Cancer - Delatestryl (Testosterone Enanthate Injection) may be used secondarily in women with advancing inoperable metastatic (skeletal) mammary cancer who are one to five years postmenopausal. Primary goals of therapy in these women include ablation of the ovaries. Other methods of counteracting estrogen activity are adrenalectomy, hypophysectomy, and/or anti-estrogen therapy. This treatment has also been used in pre-menopausal women with breast cancer who have benefited from oophorectomy and are considered to have a hormone-responsive tumor. Judgment concerning androgen therapy should be made by an oncologist with expertise in this field.

### **Testopel**

#### **Males**

Androgens are indicated for replacement therapy in conditions associated with a deficiency or absence of endogenous testosterone.

Primary hypogonadism (congenital or acquired) - testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testes syndrome: or orchiectomy.

Hypogonadotropic hypogonadism (congenital or acquired) - gonadotropic LHRH deficiency, or pituitary - hypothalamic injury from tumors, trauma or radiation.

If the above conditions occur prior to puberty, androgen replacement therapy will be needed during the adolescent years for development of secondary sex characteristics. Prolonged androgen treatment will be required to maintain sexual characteristics in these and other males who develop testosterone deficiency after puberty.

Safety and efficacy of Testopel (testosterone pellets) in men with "age-related hypogonadism" (also referred to as "late-onset hypogonadism") have not been established.

Androgens may be used to stimulate puberty in carefully selected males with clearly delayed puberty. These patients usually have a familial pattern of delayed puberty that is not secondary to a pathological disorder; puberty is expected to occur spontaneously at a relatively late date. Brief treatment with conservative doses may occasionally be justified in these patients if they do not respond to psychological support. The potential adverse effect on bone maturation should be discussed with the patient and parents prior to androgen administration. An x-ray of the hand and wrist to determine bone age should be taken every 6 months to assess the effect of treatment on epiphyseal centers.

#### **COVERAGE CRITERIA**

- Testosterone products will be covered with prior authorization when the following criteria are met:
    - The requested drug is being prescribed for primary or hypogonadotropic hypogonadism [Note: Safety and efficacy of testosterone products in patients with "age-related hypogonadism" (also referred to as "late-onset hypogonadism") have not been established.]
- AND**
- Before the start of testosterone therapy, the patient has at least two confirmed low testosterone levels according to current practice guidelines or your standard male lab reference values **OR**
  - For continuation of testosterone therapy: before the patient started testosterone therapy, the patient had a confirmed low testosterone level according to current practice guidelines or your standard male lab reference values
- OR**
- Delatestryl (testosterone enanthate injection) is being prescribed for inoperable metastatic breast cancer in a patient who is 1 to 5 years postmenopausal **AND** the patient had an incomplete response to other therapy for metastatic breast cancer
- OR**
- Delatestryl (testosterone enanthate injection) is being prescribed for a pre-menopausal patient with breast cancer who has benefited from oophorectomy and is considered to have a hormone-responsive tumor
- OR**
- Delatestryl (testosterone enanthate injection) or Testopel (testosterone propionate implant pellets) is being prescribed for delayed puberty

#### **REFERENCES**

1. Androderm [package insert]. Parsippany, NJ: Actavis Pharma, Inc.; July 2015.
2. AndroGel 1% [package insert]. North Chicago, IL: Abbvie Inc; November 2016.
3. AndroGel 1.62% [package insert]. North Chicago, IL: Abbvie Inc; October 2016.
4. Axiron [package insert]. Indianapolis, IN: Lilly USA, LLC; October 2016.
5. Delatestryl [package insert]. Malvern, PA: Endo Pharmaceuticals Solutions Inc.; May 2015.
6. Depo-Testosterone [package insert]. New York, NY: Pharmacia and Upjohn Company; November 2016.
7. Fortesta [package insert]. Malvern, PA: Endo Pharmaceuticals Inc.; October 2016.
8. Natesto [package insert]. Malvern, PA: Endo Pharmaceuticals; July 2016.
9. Striant [package insert]. Malvern, PA: Endo Pharmaceuticals.; November 2016.
10. Testim [package insert]. Chesterbrook, PA: Auxilium Pharmaceuticals, Inc.; October 2016.
11. Testopel Pellets [package insert]. Malvern, PA: Auxilium Pharmaceuticals, Inc; October 2016.
12. Vogelxo [package insert]. Maple Grove, MN: Upsher-Smith Laboratories, Inc.; November 2016.
13. AHFS DI (Adult and Pediatric) [database online]. Hudson, OH: Lexi-Comp, Inc.; [http://online.lexi.com/lco/action/index/dataset/complete\\_ashp](http://online.lexi.com/lco/action/index/dataset/complete_ashp) [available with subscription]. Accessed November 2016.
14. Micromedex Solutions [database online]. Greenwood Village, CO: Truven Health Analytics Inc. Updated periodically. [www.micromedexsolutions.com](http://www.micromedexsolutions.com) [available with subscription]. Accessed November 2016.
15. Petak S, Nankin H, Spark R, et al. American Association of Clinical Endocrinologists Medical Guidelines for Clinical Practice for the Evaluation and Treatment of Hypogonadism in Adult Male Patients – 2002 update. *Endocrine Practice* 2002;8(6):439-456.

16. Bhasin S, Cunningham G, Hayes F, et al. Testosterone Therapy in Adult Men with Androgen Deficiency Syndromes: An Endocrine Society Clinical Practice Guideline. *Journal of Clinical Endocrinology & Metabolism* 2010 95(6):2536-2559.